



1675

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): LI et al. Group Art Unit: 1635  
Serial No.: 10/038,984 Examiner: : TRACY ANN VIVLEMORE  
Filed: JANUARY 4, 2002 Docket No.: 275.0003 0102  
Confirmation No.: 9705  
Title: COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO ATTENUATION OF  
GENE EXPRESSION USING DOUBLE STRANDED RNA

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CHARGE ALL FEES TO DEPOSIT ACCOUNT 13-4895**

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

- ☒ **Small entity status is entitled to be asserted in the above-identified application.**  
☒ **An itemized return postcard.**  
☐ A Petition for Extension of Time for \_\_ month(s). Please charge Deposit Account No. 13-4895 in the amount of \$\_\_ for the required fee.  
☒ **An Information Disclosure Statement (3 pgs); 1449 forms (31 pgs); and copies of 426 documents cited on the 1449 forms. Charge Deposit Account 13-4895 the amount of \$180 to cover the required fee.**  
☐ A check in the amount of \$\_\_, representing \_\_\_\_.  
☐ Other: \_\_\_\_.  
☐ Amendment ☐ No Additional fee is required. ☐ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$25 =	
Independent Claims				x \$100 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$180 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

**CERTIFICATE UNDER 37 C.F.R. §1.8:** The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19 day of December, 2006.

MUETING, RAASCH & GEBHARDT, P.A.  
Customer Number: 26813

By: David L. Provence  
Name: David L. Provence  
Reg. No.: 43,022  
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Facsimile: 612-305-1228



PATENT  
Docket No. 275.00030102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): LI et al. ) Group Art Unit: 1635  
)  
Serial No.: 10/038,984 ) Examiner: Tracy Ann Vivlemore  
Confirmation No.: 9705 )  
)  
Filed: January 4, 2002 )  
)  
For: COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO  
ATTENUATION OF GENE EXPRESSION USING DOUBLE STRANDED  
RNA

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Pursuant to MPEP § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Applicants would also like to bring to the Examiner's attention Benitec v. Nucleonics Civil Action No. 04-CV-0174 (JJF) in the U.S. District Court for the District of Delaware. Certain documents cited herein were first brought to the Applicants' attention in a search of literature related to this action.

**Should the Examiner wish to review any documents in Applicants' possession related to this action, the Examiner is invited to contact the undersigned and any documents requested will be forwarded.**

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Documents U.S. Patent 5,578,716, WO 94/01550A1, Barlow et al., Beretta et al., Billy et al., Brand et al., Brummelkamp et al. (*Cancer Cell*, 2:243-247, (2002)), Burke et al., Haggarty et al., Harada et al., Kirchhoff et al., McManus et al. (*RNA*, 8:842-850 (2002)), Thoemis et al., listed on the attached Form PTO-1449 were cited in an Opposition of EP 1230375 B1.

Documents U.S. 5,631,148 (Urdea), and WO 99/32619 A1, of record, were also cited in the opposition.

Documents WO 95/27783 A1, WO 97/34638 A1, and Schaefer et al., listed on the attached Form PTO-1449 were cited in a foreign search or examination report corresponding to Korean application serial no. 10-2001-7013385 and mailed on August 8, 2006. This application has inventors in common with the instant application.

An English translation of non-English document, Zakharyan et al., is attached to the document. U.S. Patent 5,788,265 is being submitted as an English language equivalent of non-English document, EP 0 560 156 A2. An English abstract of non-English publications WO 92/19732 A1, WO 95/18223 A1, WO 98/05770 A2 and WO 00/44895 A1, may be found on the cover page of the publication. An English abstract of non-English publications JP 09-110894 A and JP 09-227413 may be found attached to the publication.

Since this Information Disclosure Statement is submitted after the receipt of an Office Action in the above-identified patent application, Applicants hereby authorize a charge of \$180 to Deposit Account No. 13-4895 to cover the fee required under 37 C.F.R. §§1.97(c) and 1.17(p). Please charge any additional fees or credit any overpayment to Deposit Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,

on this 19 day of Dec., 2006.

David L. Provence  
Name David L. Provence

Respectfully submitted

By

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December 19, 2006  
Date

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# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Attorney Docket No.  
275.00030102

Application No.  
10/038,984

Applicants: Li *et al.*

PAGE 1 of 31

Information Disclosure Statement Mailed :

December 19, 2006

Filing Date: January 4, 2002

Group Art Unit: 1635

PTO Form 1449

## U.S. PATENT DOCUMENTS

Initial	Copy Enclosed	Document No.	Date	Name	Class	Sub-Class	Filing Date
		US 2002/0086356 A1	07/04/2002	Tuschl <i>et al.</i>			
		US 2002/0168707 A1	11/14/2002	Graham			
		US 2003/0018993 A1	01/23/2003	Gutterson <i>et al.</i>			
		US 2003/0036197 A1	02/20/2003	Glassman <i>et al.</i>			
		US 2003/0061626 A1	03/27/2003	Plaetinck <i>et al.</i>			
		US 2003/0074684 A1	04/17/2003	Graham <i>et al.</i>			
		US 2003/0159161 A1	08/21/2003	Graham <i>et al.</i>			
		US 2003/0165894 A1	09/04/2003	Waterhouse <i>et al.</i>			
		US 2004/0022748 A1	02/05/2004	Ananthapadmanabhan <i>et al.</i>			
		US 2004/0064842 A1	04/01/2004	Graham <i>et al.</i>			
		US 2004/0138168 A1	07/15/2004	Satishchandran <i>et al.</i>			
		US 2004/0180439 A1	09/16/2004	Graham <i>et al.</i>			
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		US 2005/0250208 A1	11/10/2005	Graham <i>et al.</i>			
		US 2006/0014715 A1	01/19/2006	Graham <i>et al.</i>			
		US 3,931,397	01/06/1976	Harnden			
		US 4,130,641	12/19/1978	Ts'o <i>et al.</i>			
		US 4,283,393	08/11/1981	Field <i>et al.</i>			
		US 4,469,863	09/04/1984	Ts'o <i>et al.</i>			
		US 4,605,394	08/12/1986	Skurkovich			
		US 4,766,072	08/23/1988	Jendrisak <i>et al.</i>			
		US 5,024,938	06/18/1991	Nozaki <i>et al.</i>			
		US 5,034,323	07/23/1991	Jorgensen <i>et al.</i>			
		US 5,173,410	12/22/1992	Ahlquist			
		US 5,190,931	03/02/1993	Inouye			
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		US 5,365,015	11/15/1994	Grierson <i>et al.</i>			
		US 5,453,566	09/26/1995	Shewmaker <i>et al.</i>			
		US 5,514,546	05/07/1996	Kool			
		US 5,578,716	11/26/1996	Szyf <i>et al.</i>			
		US 5,643,762	07/01/1997	Ohshima <i>et al.</i>			
		US 5,683,985	11/04/1997	Chu <i>et al.</i>			

Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)  <b>PTO Form 1449</b>				<b>Attorney Docket No.</b> 275.00030102		<b>Application No.</b> 10/038,984	
				<b>Applicants: Li et al. PAGE 2 of 31</b>			
				<b>Filing Date: January 4, 2002</b>		<b>Group Art Unit: 1635</b>	
<b>U.S. PATENT DOCUMENTS</b>							
Initial	Copy Enclosed	Document No.	Date	Name	Class	Sub-Class	Filing Date
		US 5,686,649	11/11/1997	Chua et al.			
		US 5,691,140	11/25/1997	Noren et al.			
		US 5,693,773	12/02/1997	Kandimalla et al.			
		US 5,714,323	02/03/1998	Oshima et al.			
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		US 5,795,715	08/18/1998	Livache et al.			
		US 5,798,265	08/25/1998	Springer et al.			
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		US 6,022,863	02/08/2000	Peyman			
		US 6,054,299	04/25/2000	Conrad			
		US 6,133,024	10/17/2000	Helene et al.			
		US 6,291,504	09/18/2001	Nugiel et al.			
		US 6,369,038	04/09/2002	Blumenfeld et al.			
		US 6,372,965	04/16/2002	Lightner et al.			
		US 6,423,885	07/23/2002	Waterhouse et al.			
		US 6,531,647	03/11/2003	Baulcombe et al.			
		US 6,635,805	10/21/2003	Baulcombe et al.			
		US 09/646,807	Not Published	Graham et al.			
		US 60/117,635	Not Published	Li et al.			
		US 60/130,377	Not Published	Pachuk et al.			
Examiner			Date Considered				
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				<b>Applicants:</b> <i>Li et al.</i> <b>PAGE 3 of 31</b>			
				<b>Filing Date:</b> January 4, 2002		<b>Group Art Unit:</b> 1635	
<b>FOREIGN PATENT DOCUMENTS</b>							
Initial	Copy Enclosed	Document No.	Date	Country	Class	Sub-Class	Translation
	X	AU 200195225 A1	01/31/2002	Australia			
	X	AU 729454	02/01/2001	Australia			
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	X	CA 2012312 C	09/16/1990	Canada			
	X	CA 2370628 A1	10/26/2000	Canada			
	X	DE 199 03 713.2	Not Published	Germany			
	X	EP 0 213 921 A2	03/11/1987	Europe			
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	X	EP 0 350 151 A2	01/10/1990	Europe			
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	X	EP 0 350 151 B1	03/30/1994	Europe			
	X	EP 0 465 572 B1	06/14/1995	Europe			
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				<b>Applicants: Li et al. PAGE 4 of 31</b>			
				<b>Filing Date: January 4, 2002</b>		<b>Group Art Unit: 1635</b>	
<b>FOREIGN PATENT DOCUMENTS</b>							
Initial	Copy Enclosed	Document No.	Date	Country	Class	Sub-Class	Translation
	X	EP 0 560 156 A2	09/15/1993	Europe			No
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	X	EP 1 229 134 A3	01/28/2004	Europe			
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Examiner			Date Considered				
<b>Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							



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				<b>Applicants: Li et al.                      PAGE 5 of 31</b>			
				<b>Filing Date: January 4, 2002</b>		<b>Group Art Unit: 1635</b>	
<b>FOREIGN PATENT DOCUMENTS</b>							
Initial	Copy Enclosed	Document No.	Date	Country	Class	Sub-Class	Translation
	X	WO 97/10360 A1	03/20/1997	WIPO			
	X	WO 97/34638 A1	09/25/1997	WIPO			
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	X	WO 03/027298 A1	04/03/2003	WIPO			
	X	WO 03/056012 A1	07/10/2003	WIPO			
Examiner			Date Considered				

**Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)  <b>PTO Form 1449</b>		<b>Attorney Docket No.</b> 275.00030102	<b>Application No.</b> 10/038,984
		<b>Applicants:</b> Li <i>et al.</i> <b>PAGE 6 of 31</b>	
		<b>Filing Date:</b> January 4, 2002	<b>Group Art Unit:</b> 1635
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)</b>			
<b>Initial</b>	<b>Copy Enclosed</b>		
	X	"somatic cell," on-line medical dictionary, <a href="http://cancerweb.ncl.ac.uk/cgi-bin/">http://cancerweb.ncl.ac.uk/cgi-bin/</a> (January 2006).	
	X	Agrawal <i>et al.</i> , "RNA Interference: Biology, Mechanism, and Applications" <i>Microb. Mot. Biol. Rev.</i> 67:657-685 (2003).	
	X	Agrawal <i>et al.</i> , "Self-Stabilized Oligonucleotides as Novel Antisense Agents," in <u>Delivery Strategies: antisense oligonucleotide therapeutics</u> , Ahktar <i>et al.</i> , Eds., pp. 105-121 CRC Press, Inc., Boca Raton, Florida (1995).	
	X	Agrawal, "Antisense oligonucleotides: towards clinical trials," <i>TIBTECH</i> 14: 376-387 (1996).	
	X	Akgun <i>et al.</i> , "Palindrome Resolution and Recombination in the Mammalian Germ Line", <i>Mol. Cell. Biol.</i> 17: 5559-5570 (September 1997).	
	X	Akhtar <i>et al.</i> , "Anti-HIV therapy with antisense oligonucleotides and ribozymes: realistic approaches or expensive myths?" <i>J. Antimicrob. Chemother.</i> 38: 159-165 (1996).	
	X	Ambion, "pT7/T3 18" and "pT7/T3 19" 4 pages (date unknown).	
	X	Anderson, "Human gene therapy," <i>Nature</i> 392:25-30 (1998).	
	X	Annex A filed in EP 99 910 039.9.	
	X	Annex B filed in EP 99 910 039.9 (September 9, 2005).	
	X	Annex C filed in EP 99 910 039.9 (September 9, 2005).	
	X	Annex D filed in EP 99 910 039.9 (September 9, 2005).	
	X	Appeal against decision to refuse a European patent application issued July 11, 2005, filed in EP 99 910 039.9 (September 9, 2005).	
	X	Assaad <i>et al.</i> , "Epigenetic repeat-induced gene silencing (RIGS) in <i>Arabidopsis</i> ," <i>Plant Molecular Biology</i> 22(6): 1067-1085 (1993).	
Examiner		Date Considered	
<b>Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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		<b>Applicants:</b> Li <i>et al.</i> <b>PAGE 7 of 31</b>	
		<b>Filing Date:</b> January 4, 2002	<b>Group Art Unit:</b> 1635
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)</b>			
Initial	Copy Enclosed		
	X	Author unknown, "Breakthrough of the Year #4: Still hot," <i>Science</i> 302:2038-2045 (2003).	
	X	Bahner <i>et al.</i> , "Transduction of Human CD34 <sup>+</sup> Hematopoietic Progenitor Cells by a Retroviral Vector Expressing an RRE Decoy Inhibits Human Immunodeficiency Virus Type 1 Replication in Myelomonocytic Cells Produced in Long-Term Culture," <i>J. Virol.</i> 70:4352-4360 (1996).	
	X	Balandin <i>et al.</i> , "Silencing of a $\beta$ -1-3-glucanase transgene is overcome during seed formation," <i>Plant Molecular Biology</i> 34(1):125-137 (1997).	
	X	Barbeau <i>et al.</i> , "Characterization of the human and mouse Fli-1 promoter regions," <i>Biochim. Biophys. Acta</i> 1307: 220-232 (1996).	
	X	Barlow <i>et al.</i> , "Interferon synthesis in the early post-implantation mouse embryo," <i>Differentiation</i> 27:229-235 (1984).	
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Examiner		Date Considered	
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